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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/765,564

01/27/2004

William Dubrul

GTEC 1001-5

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EXAMINER

HOUSTON, ELIZABETH

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

12/02/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/765,564	Applicant(s) DUBRUL ET AL.	
	Examiner ELIZABETH HOUSTON	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6,7,10-16,19,20,22-25,27 and 28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6,7,10-16,19,20,22-25,27 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :10/31/07, 10/30/07, 08/22/07, 07/25/07.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/09/08 has been entered.

Claim Objections

2. Claim 15 is objected to because of the following informalities: Line 10 of claim 15 states "said the blood flow blocking". It should be corrected to state --- "*said blood flow blocking*" or "*the blood flow blocking*". Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claim 6 is rejected under 35 U.S.C. 102(b) as being anticipated by Kavteladze (WO 95/27448). (For references in rejection please refer to US patent 5,683,411)**

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5. Kavteladze discloses the invention substantially as claimed including an occluder and a method of deploying an occluder that comprises: a catheter having a distal end (C5:L40) that is inserted into a body passageway, having a balloon-less blood flow blocking element (Figs 3, 4, 6 9, 10) comprising structural members (10,11,40,41) defining openings there between (see figures) and positioned near the distal end of the catheter, said blood flow blocking element having a radially compressed insertion state and a radially expanded, passageway sealing state (C5:L38-50), , the step of radially expanding the blood flow blocking element being carried out without inflating a balloon using a fluid, and said blood flow blocking element in said radially expanded state having an outer distally facing, generally funnel surface extending out from said distal end of said catheter (10, 11, 40, 41). The blocking element completely blocks passage of material around the outside of the catheter. An annular membrane (16, 42) that contacts the structural members is an elastomeric impermeable membrane (C3:L8-15).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. **Claim 7 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kavteladze (US 5,683,411).**

8. Kavteladze does not disclose that the blood flow blocking element is malecot style. However, the instant disclosure describes this parameter as merely preferable and does not describe it as contributing any unexpected result to the occluder. As such this parameter is deemed a matter of design choice (lacking in any criticality) and well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

9. Claims 10-16, 19, 20, 22-25 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kavteladze in view of Marks (US 5,108,420).

10. Kavteladze discloses the invention substantially as claimed as stated above except for an actuator. Kavteladze further states that the device is “ejected “from the catheter indicating the use of an actuator, but does not explicitly state the use of an actuator. However Marks discloses the delivery of an occluder that uses a delivery catheter (17) and an actuator (15 and 19) that extends through the lumen of the catheter that does not require inflating a balloon. The actuator Extends distal of the blood blocking element (19 prior to deployment) and when moved in a proximal direction (C4:L21-39 states that 19 is pulled proximally while 15 is pushed), engages the blood blocking element (19 will continue to engage the occluder until it leaves the catheter as seen in Fig. 1) to switch from the retracted state to the expanded state.

It would have been obvious to incorporate an actuator to move the blood flow blocking element form the compressed state to the radially expanded state since it is well known in the art to use actuators to assist self-expanding devices out of the catheter. A person

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of ordinary skill has good reason to pursue the known options within his or her technical grasp if it yields predictable results.

11. Regarding claim 12 and 16, Kavteladze does not disclose that the blood flow blocking element is malecot style. However, the instant disclosure describes this parameter as merely preferable and does not describe it as contributing any unexpected result to the occluder. As such this parameter is deemed a matter of design choice (lacking in any criticality) and well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

Response to Arguments

12. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH HOUSTON whose telephone number is (571)272-7134. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. H./
Examiner, Art Unit 3731

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731